ADDENDUM

Appeal No. 24-1285

IN THE
United States Court of Appeals
FOR THE FEDERAL CIRCUIT

APPLE INC.,

Appellant,

v.

UNITED STATES INTERNATIONAL TRADE COMMISSION,

Appellee,

MASIMO CORPORATION, CERCACOR LABORATORIES, INC.,

Intervenors

Appeal from the United States International Trade Commission
Investigation No. 337-TA-1276

DECLARATION OF JOE KIANI IN SUPPORT OF MASIMO CORPORATION AND CERCACOR LABORATORIES, INC.'S OPPOSITION TO APPLE'S EMERGENCY MOTION TO STAY ENFORCEMENT OF ITC'S ORDER PENDING REVIEW

I, Joe Kiani, pursuant to 28 U.S.C. § 1746, declare as follows:

1. I am the founder, Chairman, and Chief Executive Officer of Masimo Corporation ("Masimo") and Chairman and Chief Executive Officer of Cercacor Laboratories, Inc. ("Cercacor") (collectively, "Masimo"). I have personal

knowledge of the matters set forth herein and if called upon to testify, I could and would competently testify thereto.

2. I submit this Declaration in support of Masimo's Opposition to Apple's Emergency Motion For Stay Pending Appeal And To Stay Enforcement Of ITC's Order Pending Review. I explain some of the hardships that Masimo, its customers, and the public as a whole would suffer if this Court were to stay the remedial orders of the United States International Trade Commission (ITC) while Apple appeals from those orders.

A. Masimo Became A World-Leading Company For Noninvasive Monitoring Through Innovation

3. Masimo is a global medical technology company that produces a wide variety of industry-leading patient monitoring technologies, including innovative measurements, sensors, and patient monitors. Masimo first succeeded in revolutionizing how patients are monitored with pulse oximetry, a non-invasive technique for determining the degree to which blood is carrying oxygen.

4. Today, Masimo leads the industry in pulse oximetry and noninvasive monitoring. Masimo manufactures and sells its pulse oximetry technology to caregivers who use it to monitor over 200 million patients a year. Masimo's technology is the standard in nine of the top ten hospitals in the United States.

5. Because of Masimo's success, today it is publicly traded and employs more than 9,000 people worldwide. Over 150 other companies integrate Masimo

technology circuit boards into their own monitors (like "Intel Inside"). Masimo's revolutionary technology came only through many years of innovation in the United States. Since I founded the company in my garage in 1989, Masimo's goal has been to improve patient outcomes, to reduce the cost of care, and to take noninvasive monitoring to new sites and applications.

6. By the mid-1990s, Masimo had proven how to reliably measure arterial oxygen saturation, even in the presence of patient motion and low blood flow. Masimo called its technology Masimo SET (Signal Extraction Technology). At the time, motion and low blood flow were known as the "bane of pulse oximetry." The leaders in the industry had given up on the problem, telling clinicians and me that it was impossible. In addition, before Masimo's pulse oximeter, no clinical outcome study had shown the value of pulse oximetry. I founded Masimo with the goal of solving this problem.

7. Numerous peer-reviewed outcome studies have shown lifesaving and life-improving outcomes with Masimo SET pulse oximetry. Among other things, Masimo pulse oximetry has been proven to reduce blindness in babies in the neonatal intensive care units, detect congenital heart defects in newborns, and save lives in post-surgical departments where lives are frequently lost because of opioid-induced respiratory depression. In addition to these outcome improvements, Masimo pulse oximetry has also been shown to reduce the cost of patient care.

8. When Masimo succeeded in solving the motion problem, the pulse oximetry field was dominated by Nellcor, now owned by Medtronic. At the time, Nellcor had maintained a virtual monopoly for over a decade. When Masimo released its first pulse oximeters, Nellcor told customers that what Masimo had done was just a trick, because it was supposedly impossible to measure accurately during motion and low perfusion. Indeed, some hospitals were told that using Masimo's technology was even dangerous.

9. When clinicians started conducting side-by-side demonstrations demonstrating Masimo's superior technology, Nellcor introduced a new pulse oximeter that a jury later found infringed Masimo's patents. That jury verdict and post-trial rulings of the judge were affirmed on appeal. Ultimately, the infringing product was removed from the market, allowing Masimo to protect its investment in its revolutionary technology, dramatically grow its sales, and ultimately flourish under the benefits provided by patent protection.

10. Masimo did not rest on its first innovations and has continued for decades to reinvest in researching and developing revolutionary technology for the benefit of patients and ultimately the public. Those investments allowed Masimo to apply pulse-oximetry principles to measure other parameters of the blood. For example, Masimo introduced this new noninvasive blood constituent monitoring technology in 2005. Masimo is still the only company to offer products that measure

the blood constituents of total hemoglobin, carboxyhemoglobin, and methemoglobin. Those products have also been shown in peer-reviewed studies to save lives. Like Masimo's pulse oximetry, Masimo circuit boards with these new technologies are made available to OEM customers to integrate into their products.

11. Innovation at Masimo continues, with new products each year. In 2023, the FDA cleared for medical use Masimo's latest innovative parameter, Oxygen Reserve Index, which is related to the patient's partial pressure of oxygen. Masimo (and its OEM customers) is the only company with this parameter.

12. In the past decade, Masimo has also been offering pulse oximetry devices with reliable medical-grade measurements directly to consumers for use outside the professional patient care environment. In 2013, Masimo created iSpO2, which allowed users to measure their oxygen saturation using Masimo's unmatched medical performance with an Apple iPhone. In 2014, Masimo released a version of iSpO2 for Android phones. In 2015, Masimo received FDA clearance for a self-contained finger pulse oximeter called MightySat Rx for clinicians. Masimo also sold a version of the MightySat with the same medical-grade pulse oximetry directly to consumers. Through these products, Masimo has made its hospital-grade technology directly available to everyone, not just in hospitals.

13. In 2022, Masimo acquired Sound United, a leading developer of premium consumer sound and home integration technologies, including consumer

electronics brands such as Bowers & Wilkins, Denon, Marantz and Polk Audio. This acquisition gave Masimo access to over 20,000 retail outlets around the world, greatly bolstering Masimo's ability to sell its medical-grade technology products directly to consumers.

14. Masimo also makes its wearable pulse oximetry modules available to other manufacturers of consumer products, similar to how Masimo works with OEM partners to offer pulse oximetry technology in their products sold to hospitals. Masimo is in discussions with many such companies. This allows more widespread availability of Masimo products.

B. Masimo's Long-Term Investments In Pulse Oximetry On The Wrist

15. Masimo traveled a very long innovation path over 30 years to create its wrist pulse oximeter. I documented my desire to offer a wrist-worn pulse oximeter in an early 1990s engineering notebook at Masimo. I testified about my idea during the hearing in this Investigation. Ex. 3 at 114:3-12, 169:16-22.[1] We could not initially develop the idea due to power and size limitations at the time. After making progress on both issues, Masimo and a spin-off of Masimo named Cercacor started investing heavily in developing and making such a product in about 2013.

[1] The cited exhibits are attached to the Declaration of Joseph Re submitted with Masimo's Opposition.

16. On its path to making a wearable medical-grade pulse oximeter for consumers, Masimo first succeeded in making wearable pulse oximeters for the hospital. In 2014, Masimo released to hospitals the Radius-7, a wearable wireless pulse oximeter where the device is strapped to a user's arm, giving the patient freedom to walk around without having to move with a separate monitor. This eliminated the wires that tether the patient to a bedside monitor. By 2019, Masimo had introduced a much smaller wrist-worn wireless pulse oximeter marketed to hospitals as the Radius PPG. That device communicates with smart devices such as smart phones and tablets with an app loaded on those devices. Although the Radius PPG is worn on the wrist, it makes its measurement from a sensor on the finger. The fingertip is an ideal location for pulse oximetry because it has a rich supply of capillaries carrying arterial blood to be measured.

17. Masimo and Cercacor have long been investigating whether the sensor could be located on various parts of the body other than the finger, including the wrist. Measuring this parameter from the wrist is far more difficult because the wrist does not have a dense capillary bed.

18. By at least as early as 2014, building on the 25 years of pulse oximetry excellence from Masimo, Cercacor was experimenting with a wireless watch-style pulse oximeter with the sensors collecting information from the wrist. By late 2019, Masimo was clinically testing something we internally called the "Air Watch." This

product measured oxygen saturation directly from the wrist and not the finger as had been traditionally done. This product eventually became known as the "Masimo W1" (hereinafter "W1"). Before the ITC, Masimo submitted its costs for developing the W1, which excluded the prior 25 years of pulse oximetry research and development that was critical to enabling the W1.

19. The development leading to the W1 occurred in the United States and most of the production takes place domestically. For example, Masimo has its own semiconductor plant in New Hampshire, where it makes light emitting diodes for the W1. The W1 is manufactured in Irvine California. The W1 has been on the market for over a year and is used for medical purposes in hospitals and homes outside the U.S. While Masimo was pursuing FDA clearance for medical use in the U.S. Masimo sold the W1 directly to consumers for non-medical uses.

20. In November 2023, Masimo received FDA clearance for both prescription and over-the-counter use of the W1 health-tracking watch, which includes continuous hospital-grade pulse oximetry. Ex. 30. Thus, the W1 became an FDA-cleared wristwatch to provide continuous real-time oxygen saturation. Because the FDA clearance was for both prescription and "over the counter" sale, the W1 is available directly to consumers without a prescription for medical use.

21. Pulse oximeters sold to consumers without FDA clearance are not for medical use. The Apple Watches do not have FDA clearance for pulse oximetry. As

discussed below, Apple has not obtained FDA clearance for its pulse oximeter even though it heavily advertises the Apple Watch for medical uses. *See*, e.g., Ex. 49, video at 11:28-12:00 (Apple 2020 Event); *see also* Ex. 36 (Apple healthcare website); Ex. 11 (Series 6 launch video).

22. Masimo is in the process of releasing a more elegant smartwatch called Freedom that includes the same pulse oximeter as in the W1, with Masimo's medical-grade pulse oximetry technology. The Freedom smartwatch has already been released in a pre-market release where users provide their feedback in exchange for favorable purchase terms. We expect to make Freedom available for sale under our limited market release program this quarter. Assuming positive feedback, Freedom is scheduled for full market release in the first half of 2024. The Freedom smartwatch will include typical smartwatch features, such as cell phone, messaging, music, and the like, in addition to a medically reliable pulse oximeter, and a hardware privacy switch.

23. As Masimo was developing ways to noninvasively measure hemoglobin and other very hard-to-measure blood constituents, such as glucose, we invented a solution for maximizing signal and reducing noise. This included a particularly shaped convex sensor with light piping reduction technology. That same technology facilitated measuring pulse oximetry on difficult-to-measure parts of the body such as the wrist. I am among the named inventors of the patents on this

innovation, which include the two patents supporting the ITC's remedial orders. As I testified in this Investigation, I am aware of only Masimo and Apple ever using this technology. Ex. 3 at 184:10-185:3. As explained below, Apple hired one of my co-inventors, Marcelo Lamego, back in 2014.

C. Masimo's History With Apple

24. In May 2013, after identifying Masimo as the "platinum" in medical monitoring technology (such as pulse oximetry), Apple met with me and another Masimo executive about integrating Masimo's technology for use in Apple's products. Ex. 12 (agenda for meeting). At this time, Apple had not introduced any watch product at all, but had, unknown to me until last year, identified pulse oximetry as an essential element to its yet-to-be-introduced watch.

25. Soon thereafter, in the summer of 2013, Apple began hiring Masimo employees, first hiring Masimo's Chief Medical Officer, a doctor hired by Masimo directly from a hospital and then trained by Masimo. By January 2014, Apple had also hired Marcelo Lamego, an engineer with deep technical understanding of Masimo's most closely held secrets. He originally worked at Masimo and then was the Chief Technical Officer of Cercacor, the Masimo spin-off. As discussed above, he is also one of the inventors on the Masimo patents supporting the remedial orders here. Over the years since 2014, Apple has hired over 20 of Masimo's engineers and employees.

26. In 2015, Apple introduced its first Apple Watch, but that product did not include pulse oximetry. While working for Apple, Masimo's former Chief Medical Officer emphatically insisted to me that Apple was not interested in pulse oximetry. He told me this when I expressed concern over Apple targeting and hiring so many Masimo employees, and he repeated it on multiple other occasions. Apple's apparent lack of interest in pulse oximetry encouraged Masimo to invest in a wrist-worn device because we thought it was an important parameter for consumers.

27. In 2019, pulse oximetry patents issued to Apple with former Masimo employees as inventors. I was shocked to learn that not only was Apple developing pulse oximetry but Apple was also attempting to patent Masimo pulse oximetry technology through Masimo's former employees. In January 2020, Masimo sued Apple in California for trade secret misappropriation and for infringement of patents not at issue before the ITC. At that time, Apple had not yet released a pulse oximeter.

28. During a public trial on Masimo's trade secret claims in 2023, I learned the following additional details about Apple's pursuit of Masimo from Apple's perspective:

(a) In 2012, Apple decided to make a watch. At the time, Apple decided pulse oximetry would be one of the most important features.

(b) In 2013, Apple recognized it was "the most clueless" in the field of "non-invasive diagnostics." Ex. 41.

(c) Apple started a program, called Rover to identify who knows pulse oximetry. Out of the list of many companies, Apple identified Masimo and Cercacor as the two standout companies, both run by me. Apple identified Masimo and Cercacor after its comprehensive search for the best patient monitoring technology. Exs. 38, 44.

(d) Apple expressed how much it liked both Masimo's technology and its leadership. Ex. 39.

(e) Apple wrote that I have a "Steve Jobs" like reputation in the medical field. Ex. 37.

(f) After Apple met with me, it commented that I was "an electrical engineer by training and was going through equations on the board with us. Solid guy." Ex. 39.

(g) Apple management wanted to acquire Masimo. Ex. 40.

(h) Apple said that it could buy the whole company for me and Masimo's cash flow. Ex. 40.

(i) Tim Cook suggested "smart recruiting."

(j) Cook rejected the acquisition. Ex. 42.

(k) In late 2013, a new project was created, called Everest to try to do a joint development, licensing, consulting or buying Masimo's people. Ex. 42.

29. After my meeting with Apple, I told Marcelo Lamego about Apple's interest in Masimo's technology. I learned through public case filings in 2022 that, on October 1, 2013, Lamego wrote to Tim Cook offering to solve Apple's difficult "patient equation" with what he had learned at Masimo and Cercacor in exchange for a "senior technical executive position" at Apple. Ex. 43. Apple responded within hours and hired Lamego. In 2023, I learned that, after hiring Lamego, Apple implemented a plan to hire "the next level down" of Masimo's employees rather than do a joint development with Masimo. Ex. 45; Ex. 59 at 12:7-13:24 (trial testimony of Apple executive Steve Hotelling).

30. In retrospect, if Apple had simply pursued what its management other than Tim Cook desired, consumers would have had quick access to world-leading pulse-oximetry technology in the Apple Watch well before 2020.

D. Masimo Sought Prompt Relief From The ITC

31. In September 2020, during the COVID pandemic, Apple introduced the Series 6 Watch with a "blood oxygen sensor." I learned last year that Apple released the blood oxygen feature to take market share from Fitbit during the "chaos of Covid", even though Apple knew that its pulse oximeter was not good enough to be used medically. Ex. 48. At the same time, Apple introduced a lower cost watch called the Apple Watch SE, which did not have a blood oxygen sensor, for $120 less

than the Apple Watch Series 6. The Apple Watch SE did include the heart-rhythm and heart-rate notification features that had been available in Apple's earlier watches.

32. I quickly saw how poorly the Apple Watch Series 6 performed pulse oximetry. I firmly believed that the importation of the foreign-made Series 6 infringes multiple Masimo patents.

33. I also knew from decades of exposure to customers in the pulse oximetry field that Apple's Series 6 Watch would harm both consumers and demand for reliable medical-grade pulse oximetry. This made time of the essence, because Apple's marketing power would quickly result in proliferation of millions of poorly performing pulse oximeters.

34. I also knew from past experiences that the United States District Courts often take several years to conduct a trial, render a final decision, and issue a final judgment with an injunction to prevent further patent infringement. In two prior patent cases, it took Masimo many years just to get to trial. I understood that the ITC typically conducts its investigations and issues its final determinations after only about 18 months. Thus, I authorized Masimo to seek an investigation by the ITC. Masimo filed its ITC complaint in July of 2021. I hoped that the ITC would promptly conduct its investigation and block the importation and sale of these Apple watches with Apple's infringing blood oxygen sensor.

35. The speed at which the ITC investigates was important to Masimo also because Masimo had been working on its medical-grade wrist pulse oximeter for some time. Masimo expected to launch the W1 during the pendency of the ITC Investigation.

36. Moreover, I knew that patents face a very limited life, especially since the law now ties the patent term to the patent's filing date, not its issuance date. This is acute for medical devices, because they take years to develop, and often require FDA clearance. I knew that the two Masimo patents underlying the ITC remedial orders expire in 2028. Thus, speed was of great importance if Masimo were to have any chance to succeed with medical-grade pulse oximetry offered to consumers that had been the subject of decades of investment.

37. Now that the ITC investigation is finally completed, as explained below, staying the ITC remedy could deprive the public of the future innovations that Masimo invests in. It could also cost Masimo its future.

38. Apple has a reputation of fighting aggressively against all patent assertions against them. Apple has made good on its reputation, with Masimo having now spent about $100 million in its dispute with Apple. That is money that could have been spent on innovation.

39. In view of Masimo's relatively small size when compared to Apple, I have essentially bet the company to get Apple to change its behavior, especially

when it comes to pulse oximetry. *See* Ex. 68 (Aaron Tilley, "The Entrepreneur Who Bet His Company On a Fight With Apple," Wall Street Journal, Jan. 2, 2024).

E. Apple's Poorly Performing Watches Hurt The Public's View Of Pulse Oximetry And, In Turn, Hurt Masimo

40. Apple strongly promotes its Series 6 and later watches for their purported ability to measure blood oxygen. Moreover, Apple markets its watches as life-saving devices. Ex. 5 (Apple's webpage for the Series 6 with the heading: "The future of health is on your wrist"); Ex. 49, video at 3:20-7:38 (Apple 2020 Event, Tim Cook introducing testimonials: "I love reading the many messages I get every day from Apple Watch users telling me how the watch…saved their lives"); Ex. 54, video at 3:11-6:23 (Apple 2022 Event, presenting customer testimonials how the Apple watch saved their lives).

41. The so-called "life-saving" features, however, are not related to the pulse oximetry. They are related to features that were already on the earlier watches, including ECG and irregular heart rhythm notifications. Moreover, Apple knows that its pulse oximetry is not medically useful. Indeed, Apple warns in fine print that its blood oxygen measurements should not be relied upon for medical purposes. *See* Ex. 10 at 11, n.1.

42. Yet, Apple marketed the Series 6 with a very heavy focus on the addition of blood oxygen measurement. Ex. 49, video at 11:28-11:55 (Apple 2020 Event, with Sumbul Desai, M.D. and Apple's VP of Health, calling blood oxygen

"like a vital sign," stating that "adding blood oxygen brings another valuable health measurement to users," and reminding viewers "blood oxygen and pulse oximetry are terms that we've heard a lot about during the COVID Pandemic.").

43. Immediately upon the release of the Series 6, the press observed that the inaccurate physiological measurements of the Series 6 watch endanger public health. One article recommended that, "[i]f you are primarily excited by the blood oxygen sensing capabilities of [Apple Watch Series 6], I would recommend instead purchasing a $20 finger tip pulse oximeter." Ex. 50 (Anthony Pearson, MD, "Should You Trust the New Apple Watch on Blood Oxygen Readings?" MedPageToday, Sept. 21, 2020). Two days later, a Washington Post article warned users: "Don't buy one of these $400 devices in the hopes of monitoring your lung health." Ex. 51 (Geoffrey Fowler, "The new Apple Watch says my lungs may be sick. Or perfect. It can't decide," Washington Post, Sept. 23, 2020). It pointed out that Apple is "conspicuously silent about accuracy." *Id*. at 2.

44. A day later, another article warned that the blood oxygen sensor was "not useful" and "not ready for prime time." Ex. 52 (Joanna Stern, "Apple Watch Series 6 and SE Review: Watch Out for the Upsell" Wall Street Journal, Sept. 24, 2020). Other articles warned that the Apple Watch gives "inconsistent results." Ex. 53 at 7 (Dieter Bohn, "Apple Watch Series 6 review: Minute improvements," The Verge 1608, Oct. 1, 2020); *see also id.* at 6 ("But because the results it provides

require so much context and are unclear so often, I trust this blood oxygen monitor way less than I trust the other sensors on the watch.").; *id.* at 5 (the "blood oxygen monitoring is unreliable" and thus included it in its list of "bad stuff" for the Apple Watch Series 6).

45. Masimo's testing of the Apple Watch confirmed how poorly it performs in measuring blood oxygen levels. As a leader in medical-grade pulse-oximetry technology, Masimo has been testing pulse oximetry technology for over 30 years. Masimo analyzed the Apple Watch Series 7's "SpO_2 accuracy based on arterial blood desaturation studies," and assessed the watch's "ability to detect SpO_2 during rapid desaturation events . . . ." Ex. 28 at 3 (Masimo Whitepaper). Masimo's study concluded that the Apple Watch would detect only 6% of desaturations, while the W1 watch detected 100% of such desaturations. *Id.* at 12. The study also concluded that: "In all cases, the Masimo W1 resulted in far superior measurement efficacy, and remains as the only commercially available wearable device capable of accurate and continuous SpO2 measurements under common clinical conditions." *Id.* at 7. The study concluded that the Apple Watch's non-continuous measurements were not capable of delivering clinical-grade SpO2 measurements. *Id.* at 9 (Masimo Whitepaper). The Apple Watch Series 7 has the same pulse oximetry as the Series 6.

46. The Apple Watch's shortcomings are especially problematic for ordinary consumers with chronic illnesses, unaware that they should not be using

the Apple pulse oximeter to manage their conditions. In contrast, the W1 reliably provides continuous measurement through about 70,000 real-time measurements a day, even when users are moving. Thus, it can detect when a medical event occurs, as well as provide a trend over time. As I learned in a public court room last year, Apple knew that its watch would only provide two measurements a day on just 37% of the people, not the 90% they had targeted. The distinction between the parties' watches is very important because prompt detection of desaturation events can be lifesaving. And detecting even less dramatic trends is helpful in detecting and diagnosing chronic illnesses.

47. An example of how the W1 continuous measurements help detect medical events comes from my own family. My daughter recently had her wisdom teeth extracted and her surgeon prescribed an opioid pain killer. In the middle of the night, her W1 showed me she was having problems breathing. I woke her up and kept her awake until the opioids had worn off. The W1 may have saved my daughter's life.

48. If an unknown company's product suffered from poor performance, it would not be as harmful. Unfortunately, because of Apple's marketing prowess, the poorly performing pulse oximetry in its watches hurts the public who rely on the deficient pulse oximeter and hurts the public's confidence in the blood oxygen parameter in general.

49. The poor performance of Apple's blood oxygen sensor is exhibited in many ways, including the poor availability of the pulse oximetry measurement, its inability to work on many users, and the limitations Apple places on how it is used. Those limitations require users to be still and to hold their wrists horizontally for a period of time while waiting for a single blood oxygen measurement. And as mentioned, because the watches are occasional spot-check devices, they do not meaningfully detect any acute desaturation events.

50. Because the proliferation of the Apple Watch, with tens of millions already sold, consumers are much more likely to be exposed to pulse oximetry and to measure their own oxygen saturation for the first time using an Apple Watch. Unfortunately, if consumers then conclude this is as good as it gets, because it came from Apple, that conclusion destroys demand for Masimo's reliable medical-grade pulse oximetry, because millions will never try it because of their initial exposure to the Apple Watch.

51. Because Masimo has always been focused on the importance of accurate and reliable blood oxygen measurements, the public's positive perception of the parameter is vital to Masimo's success.

F. Apple's Watch Harms Masimo's Sales Opportunities

52. Each time Apple sells a watch with its infringing pulse oximetry feature, it diminishes Masimo's ability to sell its competing pulse oximetry products.

It also takes away Masimo's chance to spread its name and grow its business from referrals of customers who experience Masimo's reliable pulse oximetry.

53. Moreover, consumers and clinicians pay only an extra $120-$150 for the Apple Watch with pulse oximetry compared to the Apple Watch SE without pulse oximetry. As a result, those consumers may assume pulse oximetry is worth only $120-$150. They do not know a reliable medical-grade spot-check pulse oximeter sells for over $250 and medical-grade continuous pulse oximeters (like the Masimo W1) are typically sold for several thousand dollars. Thus, consumers who buy the Apple Watch will be less inclined to investigate and consider purchasing Masimo's true medical-grade pulse oximeter with FDA clearance that sells for $500.

54. Apple also markets its watches specifically to clinicians on its healthcare website. *See, e.g.*, Ex. 36 (Apple's Healthcare Website). Apple's marketing of a non-medical-grade pulse oximeter to the healthcare community hinders Masimo's ability to sell consumer wearable products with reliable medical-grade pulse oximetry. When doctors use the Apple Watch pulse oximeter on consumers, they convey confidence in the product's quality and reliability. *See, e.g.*, Ex. 26 at 1 (Patient Safety Movement Foundation Public Interest Statement). As a result, Masimo loses sales opportunities from both the doctors and their patients.

G. A Stay Would Greatly Hurt Masimo's Reputation

55. A stay of the ITC orders would greatly hurt Masimo's name and reputation. The public knows that the Commission ruled that Apple's watches with the blood oxygen sensor infringed Masimo's patents. The news of the exclusion order has been prolific and worldwide. Granting a stay would wrongly suggest to the uninformed public that Masimo's claims may be without merit.

56. In fact, Apple has already publicized and tried to capitalize on this Court's interim stay. After the interim stay, Apple immediately told media outlets that Apple was "thrilled to return the full Apple Watch lineup to customers in time for the new year." Ex. 65 at 2; Ex. 67 at 1. Apple used the granting of the interim stay to tout that it "worked tirelessly over many years to develop technology that empowers users with industry-leading health, wellness and safety features." Ex. 65 at 2.

57. Apple has also made false claims that Masimo somehow copied Apple's technology. Apple made such assertions during the ITC proceedings. Ex. 18 at 4 (Apple's Post-Hearing Brief, Public, EDIS Doc. ID 780239). Apple also did so in its October 2022 lawsuit against Masimo in the District of Delaware. Exs. 56, 57. The Complaints alleged: "Rather than innovating and developing [its Masimo W1] independently, Masimo copied Apple while filing lawsuits to try to prevent sales of Apple Watch." Ex. 56 at ¶ 3; Ex. 57 at ¶ 3.

58. Apple also makes similar claims in the press, including before major events in this case. For example, Apple filed the Delaware case just before the ITC was supposed to render its initial determination. Apple also apparently provided its Delaware complaint to a major news outlet, Reuters, before it was filed to amplify Apple's false narrative about Masimo copying Apple. *See, e.g.* Ex. 55 (Apple claiming the W1 "copies Apple Watch and infringes [Apple] intellectual property"). In this article, Apple argued that, "by launching a device that copies Apple Watch and infringes our intellectual property, Masimo attempted to take advantage of our teams' many innovations." *Id.* at 3. But Masimo is a leading pulse oximetry company in the world with over 30 years of research and development on pulse oximetry. Masimo would never copy Apple's poorly performing product or release such a product to the public.

59. A day after the Presidential Review Period in this case expired, the press continued to repeat Apple's assertion that "it doesn't steal technology" and continued to report that Apple "accused Masimo of copying it." Ex. 62 (Wall Street Journal article). The next day, this Court granted Apple a temporary stay, and the publicity of that ruling added further confusion. *See* Ex. 66 (Aaron Tilley, "Banned Apple Watches Are Back On Sale," Wall Street Journal 1, Dec 28, 2023); *see also* Ex. 64 ("Apple Wins Legal Victory as Court Lifts Watch Ban," Dec. 27, 2023).

60. Apple's public messaging to the press tarnishes Masimo's name and reputation. Staying the ITC remedial orders will only exacerbate that harm to Masimo.

H. Apple's Ongoing Infringement Hurts Masimo's Incentive To Innovate

61. Masimo depends on the U.S. patent system to protect its innovations. Masimo has done so throughout the history of the company. That is particularly important for medical companies like Masimo because our products take longer to develop and face regulatory hurdles on top of the research and development. Masimo does not license or monetize its patents, despite many having urged me to do so. Instead, as discussed, Masimo sells circuit boards for other companies to incorporate into their own monitors. Masimo enforces its patents only against others competing against Masimo with Masimo's own inventions.

62. For example, once Masimo solved the "unsolvable" problem of measuring oxygen saturation through motion and low perfusion, companies in the pulse oximetry industry copied Masimo's technology instead of partnering with Masimo. Masimo was able to gain traction in the industry only after successfully enforcing its patent rights against the industry giants of that time.

63. Eventually, as found by a court in Delaware, "an entire industry—other than Philips and one Chinese company—took licenses from Masimo for innovative technology that saved thousands of lives and billions of dollars in healthcare costs."

Masimo Corp. v. Philips Elec. N. Am. Corp., No. CV 1:09-cv00080-LPS, 2015 WL 2379485 at *19 (D. Del. May 18, 2015). After Masimo prevailed in Delaware against Philips, Philips finally agreed to integrate more Masimo circuit boards in its products as an OEM partner. The above-referenced "Chinese company" also agreed to incorporate Masimo technology in its monitors.

64. Cash rich companies like Apple have concluded it is easier and less expensive to infringe than to innovate. A former Apple attorney has referred to this practice as "efficient infringement." Ex. 46 (Economist, "The Trouble With Patent-Troll-Hunting). This attorney went so far as to argue that for companies like Apple, "efficient infringement" could be argued to be part of an executive's fiduciary duties. *Id.*

65. For smaller companies like Masimo who innovate, enforcing patents is vital to introduce products, advance the field, level the playing field to enhance competition and incentivize further investment in innovation. For example, Masimo relied on its patents to obtain early funding from venture capital firms. Without strong patent rights, Masimo would not have been able to raise the capital necessary to create the many important and life-saving innovations discussed above.

66. Masimo and its scientists and engineers who conduct Masimo's research and development know that their work is protected by the patent system. Masimo's employees have already been demoralized by the lengthy period between

Masimo's filing of the ITC Complaint and the issuance of the ITC remedy, especially because Masimo invested so many resources in wearable medical-grade pulse oximetry. Failing to enforce Masimo's patents now further demoralizes and reduces the incentive for these talented scientists and engineers to create innovative solutions to various medical problems.

67. These scientists and engineers become demoralized when others never realize that they innovated new products and technologies that could save lives. Scientists and engineers at other companies may similarly lose their incentives to innovate if they see that large companies like Apple can infringe on patents with impunity.

68. Masimo's employees also understood that Apple hired Marcelo Lamego and Masimo's former Chief Medical Officer. In late December, Bloomberg reported on their involvement in developing technology for the Apple Watch. Ex. 63 (article reprinted in Orange County Register on Jan. 7, 2024). The Masimo scientists and engineers are demoralized knowing that some of their own colleagues assisted Apple in making a competing product. And those scientists and engineers will be further demoralized if Apple obtains a stay and is allowed to continue selling that competing product while its appeal is pending.

69. After the Commission found infringement of Masimo's patents and the USPTO denied Apple's attempt to invalidate the same Masimo patents, I, like

Masimo's others engineers, thought the time had finally come for Apple to be held accountable. I hoped that Apple would finally have to respect intellectual property and Masimo could enjoy the benefits of its patent rights. Further delay caused by a stay of the ITC orders, especially one lasting until this Court decides Apple's appeal, would be disheartening and harmful to Masimo and its incentives to keep innovating.

I. Apple Has Unfairly Benefited From Delays At The ITC While Harming Masimo

70. Although I knew that a thorough review of the evidence takes time, I was still dismayed each time that the Initial Determination (ID) and the final decision were postponed. The original target date for the ID was August 16, 2022, but that was postponed four times, and the ID was not issued until January 10, 2023. Then, on review to the full Commission, the final decision was postponed several times, resulting in an additional five-month delay to the date the Commission issued its Final Decision on October 26, 2023.

71. Those postponements cost Masimo nearly a year without relief from the harm that Apple's infringing pulse oximetry was causing. With the 60-day Presidential review period, the ITC's orders did not become effective until December 26, 2023. The postponements allowed Apple to become further entrenched using its infringing pulse oximeter. Moreover, with each passing day, Masimo's patent terms are getting closer to expiration in 2028.

72. Apple has known of the serious risk of an import ban of its infringing watches since July 2021 when Masimo filed its ITC complaint requesting the recently issued remedial orders. Nevertheless, during the prolonged ITC proceedings through the final decision on October 2023, Apple never introduced any attempted redesign. Nor did Apple move its manufacturing to the US to avoid an ITC ban. Rather, Apple introduced several new watch models (Apple's Series 7, 8, 9 Watches and Ultra and Ultra 2 Watches), all with the infringing blood oxygen sensors.

73. Despite Apple's fine-print not use its watch medically, I learned during the public portion of one of our proceedings that Apple knew that consumers would use it this way. Ex. 58 at 18:14-19:15. And, as discussed above, Apple was heavily marketing its watches as "life-saving devices" despite their poor performance. Because of Apple's wide proliferation of the infringing Apple Watch pulse oximeter, any attempt by Masimo to correct consumers' misunderstandings about pulse oximetry is being harmed with each passing day the remedial orders are not in effect.

74. Apple has also been widely publicizing that it claims to have a work around to replace the infringing watches and has instituted a proceeding before the United States Customs and Border Protection (CBP) to get permission to sell its modified watch despite the ITC orders. *See* Ex. 60 (Reuters); Ex. 61 (Time). I have been precluded from learning any details concerning Apple's supposed work-around

because Apple demanded the lawyers enter into confidentiality agreements precluding me and the public from learning about it. A stay would disrupt Apple's incentive to create a non-infringing technology. A stay will allow Apple to keep litigating as it tries to run out the clock on Masimo's patent terms.

J. Exclusion Of The Apple Watch Is In The Public Interest

75. I firmly believe a stay would be against the public's interest. Masimo is, like many other innovative companies around this country, tiny in comparison to the big tech companies. Almost all smaller innovative companies rely on the patent system and applaud strong patent enforcement. Indeed, I have received so many messages from investors and these types of companies expressing their absolute pleasure that Masimo was able to stand up to the largest company in the world and rightfully enforce patents.

76. During the ITC proceedings, the Commission sought information how an exclusion order would impact the public interest. Many organizations, doctors, lawyers, scientists, investors and concerned citizens submitted statements that confirm my testimony above, particularly those which show why exclusion is in the public's interest. These statements show that continuing to exclude Apple's infringing watches now would stop consumers from unwittingly relying on their blood oxygen saturation numbers from the Apple Watch. The public should not be relying upon the pulse oximetry in Apple's watches.

77. For example, Dr. Ward explained that he was "also very concerned about the proliferation of 'medical devices' like the Apple Watch with pulse oximetry." Ex. 23 at 2. He elaborated that:

> I have serious concerns regarding patients treating an Apple Watch pulse oximeter as a medical device when such use has not been cleared by the FDA. Patients typically rely on large household brand-name technical companies like Apple to provide products that are beneficial, and not simply contain novelty features. Apple's advertising of these medical functionalities appears to be an attempt to mislead the public into purchasing the devices as if it were a medical aid.
> …
> Although using blood oxygen saturation is useful for a physician, that does not mean the Apple Watch is capable of providing meaningful data–in my view it is not the type of device patients or physicians should rely upon for any medical purpose.
> …
> Thus, I believe Apple's insinuation in [Apple's launch] video that its watch is capable of providing 'an indication how well [your cardiovascular system] is functioning and of your overall respiratory and cardiac health' endangers public health. These current parameters provided and advertised by Apple simply do not have the fidelity and accuracy required for medical decision making.

Id. at 2-3.

78. The Medical Device Manufacturers Association (MDMA) submitted a public interest statement. The MDMA explained "A recent article comparing the Masimo W1 to the Apple Watch explains that the 'Masimo W1 feels like a tool' contrasting that to the Apple Watch as more like a toy." Ex. 27 at 2. The MDMA also explained that it "believes that protecting intellectual property rights is

particularly important in medical technology, where innovation has saved countless lives and improved the quality of life for countless others." *Id.* at 4.

79. Dr. Goldstein, a neonatologist at Loma Linda University Medical Center, explained that "the use of devices such as the Blood Oxygen feature in Apple Watches since the release of the Series 6, which does not include medical-grade technology for continuous measurement of oxygen saturation levels, damages public health and welfare." Ex. 24 at 1. He further elaborated:

> In contrast to Masimo's cutting-edge technology, the oxygen saturation measurement feature found in the Apple Watch does little, if anything, to aid the health and welfare of the public. Apple recognizes that its blood oxygen measurements are 'not intended for medical use and are only designed for general fitness and wellness purposes. But, pulse oximetry is an essential medical measurement, sometimes considered the 'fifth vital sign.' Apple does not show in its commercial advertising—except in the small print—that its pulse oximetry feature is not medically useful. I have met physicians who believe the Apple Watch must contain medical-grade pulse oximetry technology simply because it is sold by Apple and advertised as a beneficial health feature. Yet numerous commentators have written about the inaccuracy of the Apple Watch's measurements. The incorrect perception that Apple's pulse oximetry feature includes reliable technology could lead to both false positives and false negatives, hurting the public welfare.

Id. at 4.

80. Dr. Pronovost explained how "the Apple Watch is insufficient for patients, catching less than 7% of the dangerous desaturation events, compared [sic] to the Masimo W1 catching 100% of such events." Ex. 25 at 3. He continued "By detecting such a low percentage of desaturations, the Apple Watch is simply not

reliable enough to be useful." *Id.* He explained the risks of using such as device because it "could result in false negatives, underdiagnosed hypoxemia and false positives where people may unnecessarily seek healthcare and cause psychological distress." *Id* at 5. Dr. Pronovost concluded, "In sum, the Apple watch pulse oximeter is not medical grade, yet people claim to be using it as medical device, potentially causing harm." *Id.*

81. The Patient Safety Movement Foundation (PSMF) submitted a public interest. PSMF explained it "believes that devices like the Apple Watch, which do not offer hospital-grade pulse oximetry functionality, are potentially dangerous to the public, particularly given Apple's historic marketing of the feature." Ex. 26 at 1. The PSMF further explained that "If Apple says the device measures blood oxygen saturation, most consumers will not question that." *Id.* The PSMF continued, "Apple's touting of the device during the COVID pandemic, despite the lack of validation as providing clinically meaningful data to patients posed a risk to any individual who sought to use the device as a way of protecting themselves from the adverse consequences of COVID." *Id.* at 2. The PSMF elaborated:

> In my opinion, this [study] data indicates that the blood oxygen sensor in the Apple Watch does nothing beneficial for the public welfare.
>
> It is also not clear that any of the other features of the Apple Watch offer a net benefit to the public health. Although I have read anecdotal reports of people with Apple Watches believing it led to them getting checked out for a heart issue or it contacted authorities after a crash, it is not clear whether those beneficial incidents are merely random or that they justify the significant false positives. To

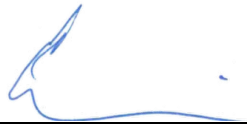
> the extent the watch is alerting authorities when there is no danger or sending users to emergency rooms when they are perfectly healthy, there is a huge societal cost.

Id. at 3-4.

82. Masimo also employs many people in the United States to produce the W1. Some parts for the W1 sensors are made in Masimo's semiconductor manufacturing facility in New Hampshire, as are parts of the MW-1 biosensing module. As mentioned above, the W1 watches are manufactured in Irvine, California. We pay fair wages to people and provide them with good working conditions hoping that they remain loyal Masimo employees. Our hope is to sell our products and not get crushed by Apple, even though Apple's watches perform poorly and are completely foreign-made using cheap labor subject to documented poor working conditions. A book called "Dying for an iPhone," documents some of these conditions. Ex. 47 ("Dying for an iPhone"). Thus, a stay would be against the interest of Masimo's employees and the public's interest in Masimo creating important jobs in America while improving public healthcare.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

Executed on January 10, 2023 at Irvine, California.



Joe Kiani

Appeal No. 24-1285

IN THE

United States Court of Appeals

FOR THE FEDERAL CIRCUIT

APPLE INC.,

Appellant,

v.

UNITED STATES INTERNATIONAL TRADE COMMISSION,

Appellee,

MASIMO CORPORATION, CERCACOR LABORATORIES, INC.,

Intervenors

Appeal from the United States International Trade Commission
Investigation No. 337-TA-1276

DECLARATION OF JOSEPH R. RE IN SUPPORT OF MASIMO CORPORATION AND CERCACOR LABORATORIES, INC.'S OPPOSITION TO APPLE'S EMERGENCY MOTION TO STAY ENFORCEMENT OF ITC'S ORDERS PENDING REVIEW

I, Joseph R. Re, pursuant to 28 U.S.C. § 1746, declare as follows:

1. I am a partner at Knobbe Martens Olson & Bear LLP, counsel of record to Intervenors Masimo Corporation and Cercacor Laboratories, Inc. in the above-captioned appeal. I have personal knowledge of the facts set forth below.

I. CITED EXHIBITS FILED IN THE 1276 INVESTIGATION

2. Attached hereto as Exhibit 1 (filed under seal) is a true and correct copy of Exhibit 21 (CAD drawings) attached to Masimo's First Amended Complaint filed on July 7, 2021 in Investigation No. 337-TA-1276, *In the Matter of Certain Light-Based Physiological Measurement Devices and Components Thereof* (hereinafter "1276 Investigation"). This exhibit is referenced in paragraph 89 of that Complaint at Stay-Add-505 to the Selwyn Declaration filed in this action. This exhibit contains confidential information and no public version of this document is currently available.

3. Attached hereto as Exhibit 2 (filed under seal) is a true and correct copy of Order No. 31: Denying Respondent's Motion for Sanctions, filed on April 28, 2022, in the 1276 Investigation. This exhibit contains confidential information, which has been redacted in the public version in the record in the 1276 Investigation.

4. Attached hereto as Exhibit 3 (filed under seal) is a true and correct copy of excerpts of the June 6, 2022 Trial Transcript of the 1276 Investigation. This

exhibit contains confidential information, which has been redacted in the public version in the record in the 1276 Investigation.

5. Attached hereto as Exhibit 4 (filed under seal) is a true and correct copy of excerpts of the June 7, 2022 Trial Transcript of the 1276 Investigation. This exhibit contains confidential information, which has been redacted in the public version in the record in the 1276 Investigation.

6. Attached hereto as Exhibit 5 is a true and correct copy of exhibit CX-0252, which is a website page for the Apple Watch Series 6 from December 28, 2020.

7. Attached hereto as Exhibit 6 (filed under seal) is a true and correct copy of Exhibit CX-375C which is a Masimo email string attaching drawings of RevA. This exhibit contains confidential information and no public version of this document is currently available.

8. Attached hereto as Exhibit 7 (filed under seal) is a true and correct copy of excerpts of exhibit CX-378C, a Masimo document showing clinical studies on RevA watches. This exhibit contains confidential information and no public version of this document is currently available.

9. Attached hereto as Exhibit 8 (filed under seal) is a true and correct copy of exhibit CX-433C, a Masimo design document showing the RevD design. This

exhibit contains confidential information and no public version of this document is currently available.

10. Attached hereto as Exhibit 9 (filed under seal) is a true and correct copy of excerpts of exhibit CX-494C, a Masimo document showing clinical studies on RevE watches. This exhibit contains confidential information and no public version of this document is currently available.

11. Attached hereto as Exhibit 10 is a true and correct copy of exhibit CX-1287, which is an Apple press release entitled "Apple Watch Series 6 delivers breakthrough wellness and fitness capabilities," dated September 15, 2020.

12. Attached hereto as Exhibit 11 is a true and correct copy of exhibit CX-1451, which is a two-minute video advertisement for the Apple Watch Series 6 shown at the time that watch was launched in September 2020. This exhibit is submitted herewith on a physical thumb drive for viewing.

13. Attached hereto as Exhibit 12 is a true and correct copy of an email from Apple executive Adrian Perica to Masimo executive Paul Jansen setting forth the agenda for an upcoming meeting between Apple and Masimo, which was admitted in the 1276 Investigation but later made public as JTX-559 in the trial of *Masimo Corp. v. Apple Inc.*, Case No. 8:20-cv-00048-JVS-JDE (C.D. Cal) in April 2023 (hereinafter the "California Action").

14. Attached hereto as Exhibit 13 (filed under seal) is a true and correct copy of exhibit CPX-52aC, showing photographs of Masimo's RevA device. This exhibit contains confidential information and no public version of this document is currently available.

15. Attached hereto as Exhibit 14 (filed under seal) is a true and correct copy of exhibit CPX-58aC, showing photographs of Masimo's RevD device. This exhibit contains confidential information and no public version of this document is currently available.

16. Attached hereto as Exhibit 15 (filed under seal) is a true and correct copy of exhibits CPX-19aC, CPX-20aC, and CPX-65aC showing photographs of Masimo's RevE devices. This exhibit contains confidential information and no public version of this document is currently available.

17. Attached hereto as Exhibit 16 (filed under seal) is a true and correct copy of excerpts of Exhibit RX-1209C in which Apple designated deposition testimony from Stephen Scruggs and introduced at the hearing in the 1276 Investigation. This exhibit contains confidential information and no public version of this document is currently available.

18. Attached hereto as Exhibit 17 (filed under seal) is a true and correct copy of excerpts of Complainants' Corrected Initial Post-Hearing Brief dated July 6,

2022 in the 1276 Investigation. This exhibit contains confidential information, which has been redacted in the public version in the record in the 1276 Investigation.

19. Attached hereto as Exhibit 18 is a true and correct copy of excerpts of the public version of Respondent Apple Inc.'s Second Corrected Post-Hearing Brief dated September 2, 2022 and filed September 14, 2022 in the 1276 Investigation.

20. Attached hereto as Exhibit 19 is a true and correct copy of the January 24, 2023 decision of the United States Patent and Trademark Office, Patent Trial and Appeal Board (PTAB) Denying Institution of Apple's Petition No. IPR2022-01273 requesting Inter Partes Review of claims 1-30 of U.S. Patent No. 10,912,502. This was Appendix F to Masimo's Response to Apple's Petition for Review, filed on January 31, 2023 in the 1276 Investigation.

21. Attached hereto as Exhibit 20 is a true and correct copy of the January 24, 2023 decision of the United States Patent and Trademark Office, Patent Trial and Appeal Board (PTAB) Denying Institution of Apple's Petition No. IPR2022-01274 requesting *Inter Partes* Review of claims 1-30 of U.S. Patent No. 10,912,502. This was Appendix C to Masimo's Response to Apple's Petition for Review, filed on January 31, 2023 in the 1276 Investigation.

22. Attached hereto as Exhibit 21 is a true and correct copy of the January 30, 2023 decision of the United States Patent and Trademark Office, Patent Trial and Appeal Board (PTAB) Denying Institution of Apple's Petition No.

IPR2022-01275 requesting *Inter Partes* Review of claims 1-30 of U.S. Patent No. 10,945,648. This was Appendix D to Masimo's Response to Apple's Petition for Review, filed on January 31, 2023 in the 1276 Investigation.

23. Attached hereto as Exhibit 22 is a true and correct copy of the January 30, 2023 decision of the United States Patent and Trademark Office, Patent Trial and Appeal Board (PTAB) Denying Institution of Apple's Petition No. IPR2022-01276 requesting *Inter Partes* Review of claims 1-30 of U.S. Patent No. 10,945,648. This was Appendix A to Masimo's Response to Apple's Petition for Review, filed on January 31, 2023 in the 1276 Investigation.

24. Attached hereto as Exhibit 23 is a true and correct copy of a public interest statement of non-party Dr. Kevin R. Ward, Professor in the Departments of Emergency Medicine and Biomedical Engineering at the University of Michigan, dated February 22, 2023 and filed in the 1276 Investigation.

25. Attached hereto as Exhibit 24 is a true and correct copy of a public interest statement of non-party Dr. Mitchell Goldstein, Professor of Pediatrics at Loma Linda University School of Medicine, dated February 24, 2023 and filed in the 1276 Investigation.

26. Attached hereto as Exhibit 25 is a true and correct copy of a public interest statement of non-party Dr. Peter Pronovost, Chief Quality & Clinical

Transformation Office at University Hospitals, dated February 26, 2023 and filed in the 1276 Investigation.

27. Attached hereto as Exhibit 26 is a true and correct copy of a public interest statement of non-party Patient Safety Movement Foundation, signed by Dr. Michael Ramsay, dated February 27, 2023 and filed in the 1276 Investigation.

28. Attached hereto as Exhibit 27 is a true and correct copy of a public interest statement of non-party Medical Device Manufacturers Association (MDMA), signed by Mark Leahey, President & CEO of MDMA, dated February 27, 2023 and filed in the 1276 Investigation.

29. Attached hereto as Exhibit 28 is a true and correct copy of Masimo's Whitepaper entitled "Masimo W1 Hospital Grade Continuous Monitoring of SpO2 and Other Parameters in a Consumer Watch." On June 5, 2023, Masimo submitted this Whitepaper as Exhibit 2 to Masimo's Submission in Response to the Commission's May 15, 2023 Notice of Commission Determination to Review In Part.

30. Attached hereto as Exhibit 29 (filed under seal) is a true and correct copy of excerpts of Complainant's Reply to Apple, Inc.'s Response to the Commission's Notice to Review in Part a Final Initial Determination and Request for Written Submissions, filed June 12, 2023 in the 1276 Investigation. This exhibit

contains confidential information, which has been redacted in the public version in the record in the 1276 Investigation.

31. Attached hereto as Exhibit 30 is a true and correct copy of Complainants' Request for Judicial Notice of Recent Regulatory Developments for Masimo W1 Watch, filed on November 20, 2023 in the 1276 Investigation.

II. OTHER CITED EXHIBITS

32. Attached hereto as Exhibit 31 is a true and correct copy of an article written by Jeremy Horowitz for Venture Beat, entitled "Apple's former top lawyer: $1 billion budget enabled high-risk strategies," dated June 10, 2019.

33. Attached hereto as Exhibit 32 is a true and correct copy of redacted excerpts of an email chain culminating in an email from Apple employees Sara Tavakoli to David Fang, dated August 6, 2020, which was admitted as JTX-358C in the California Action.

34. Attached hereto as Exhibit 33 is a true and correct copy of excerpts of Respondent Apple Inc.'s Emergency Motion to Suspend Any Remedy or Extend the Target Date and Stay Proceedings Pending Resolution of Any Appeal of the Patent Office's Decision That [Three AliveCor Patents] Are Unpatentable dated December 7, 2022 and filed in the matter of *Certain Wearable Electronic Devices with ECG Functionality and Components Thereof*, No. 337-TA-1266.

35. Attached hereto as Exhibit 34 is a true and correct copy of an excerpted version of Plaintiff Apple Inc.'s Opening Brief in Support of its Motion for Expedited Trial filed on February 10, 2023 in *Apple v. Masimo Corp.*, Case No. 22-1377-MN (D. Del) (hereinafter the "Delaware Actions").

36. Attached hereto as Exhibit 35 is a true and correct copy of an email exchange between counsel for Masimo and counsel for Apple dated December 21 and 28, 2023, where the parties have agreed that nothing in the Commission's Opinion denying Apple's Motion to Stay in the 1276 Investigation requires redactions.

37. Attached hereto as Exhibit 36 is a true and correct copy of the Apple healthcare website, https://www.apple.com/healthcare/apple-watch/, printed on January 4, 2024. On page 7 of this Exhibit, Apple compares Apple Watch models and the various features contained in each model.

III. ADDITIONAL EXHIBITS CITED IN KIANI DECLARATION

38. Attached hereto as Exhibit 37 is a true and correct copy of an email exchange culminating in an email from Apple employees James Foster to David Affourtit dated January 22, 2013, which was admitted as JTX-648 in the California Action.

39. Attached hereto as Exhibit 38 is a true and correct copy of a May 30, 2013 email from Apple employees Steve Hotelling to Heidi Delgado attaching

excerpts of a slide deck concerning Project Rover dated January 23, 2013 which was admitted as JTX-260 in the California Action.

40. Attached hereto as Exhibit 39 is a true and correct copy of a May 2013 email exchange among Apple executive Adrian Perica, Bob Mansfield, and James Foster, which was admitted as JTX-393 in the California Action.

41. Attached hereto as Exhibit 40 is a true and correct copy of a June 27, 2013 email exchange from Apple executives Adrian Perica to Paul Oppenheimer, which was admitted as JTX-395 in the California Action.

42. Attached hereto as Exhibit 41 is a redacted copy of an email exchange between Apple executives Tim Cook and Adrian Perica dated between June 29 and July 3, 2013, which was admitted as JTX-316 in the California Action.

43. Attached hereto as Exhibit 42 is a redacted true and correct copy of an email exchange culminating in an email from Apple executive Adrian Perica to Apple executive Steve Hotelling and Apple employee Debbie Lambert dated September 11, 2013, which was admitted as JTX-317 in the California Action.

44. Attached hereto as Exhibit 43 is a true and correct copy of an email from former Cercacor Laboratories, Inc. CTO Marcelo Lamego to Apple CEO Tim Cook dated October 2, 2013, and Apple's response from Apple employee David Affourtit of the same day, which was admitted as JTX-1719 in the California Action.

45. Attached hereto as Exhibit 44 is a true and correct copy of excerpts from an Apple slide deck entitled "Project Everest" last revised October 16, 2013, which was admitted as JTX-263 in the California Action.

46. Attached hereto as Exhibit 45 is a redacted true and correct copy of a string of emails starting with an email from Apple employee Lan Nguyen to Apple executive Steve Hotelling regarding "Recruiting from Masimo" dated October 22, 2013, which was admitted as JTX-2070 in the California Action.

47. Attached hereto as Exhibit 46 is a true and correct copy of an article from The Economist entitled "The Trouble With Patent-Troll-Hunting," dated December 14, 2019.

48. Attached hereto as Exhibit 47 is a true and correct copy of excerpts from a book, authored by Jenny Chan, Mark Selden and Pun Ngai, entitled "Dying for an iPhone – Apple, Foxconn, and the lives of China's workers," published in 2020.

49. Attached hereto as Exhibit 48 is a true and correct copy of a March 2020 email exchange between Apple employees Steve Waydo and Xiao Jin which was admitted as JTX-736 in the California Action.

50. Attached hereto as Exhibit 49 is a true and correct copy of an hour-long video for Apple's 2020 Event shown at the time the Apple Watch Series 6 was

launched in September 2020. This is submitted herewith on a physical thumb drive for viewing.

51. Attached hereto as Exhibit 50 is a true and correct copy of an article written by Anthony Pearson, MD for MedPageToday entitled "Should You Trust the New Apple Watch on Blood Oxygen Readings? – The Skeptical Cardiologist peels back the hype," dated September 21, 2020.

52. Attached hereto as Exhibit 51 is a true and correct copy of an article written by Geoffrey A. Fowler for the Washington Post entitled "The new Apple Watch says my lungs may be sick. Or perfect. It can't decide," dated September 23, 2020.

53. Attached hereto as Exhibit 52 is a true and correct copy of an article written by Joanna Stern for the Wall Street Journal entitled "Apple Watch Series 6 and SE Review: Watch Out for the Upsell," dated September 24, 2020.

54. Attached hereto as Exhibit 53 is a true and correct copy of an article written by Dieter Bohn for the Verge entitled "Apple Watch Series 6 review: minute improvements," dated October 1, 2020.

55. Attached hereto as Exhibit 54 is a true and correct copy of an hour-long video for Apple's 2022 Event shown at the time the Apple Watch Series 8 was launched and the Series 6 and 7 were previously launched. This is submitted herewith on a physical thumb drive for viewing.

56. Attached hereto as Exhibit 55 is a true and correct copy of an article written by Blake Brittain for Reuters entitled "Apple lawsuits say health monitoring company Masimo copied Apple Watch," dated October 20, 2022.

57. Attached hereto as Exhibit 56 is a true and correct copy of excerpts from Apple's first Complaint in the Delaware Actions filed on October 20, 2022.

58. Attached hereto as Exhibit 57 is a true and correct copy of excerpts from Apple's second Complaint in the Delaware Actions filed on October 20, 2022.

59. Attached hereto as Exhibit 58 are excerpts of the unsealed testimony of Apple employee Stephen Waydo at the trial from the California Action, dated April 19, 2023.

60. Attached hereto as Exhibit 59 are excerpts of the unsealed testimony of Apple executive Steve Hotelling given at the trial from the California Action, dated April 20, 2023.

61. Attached hereto as Exhibit 60 is a true and correct copy of an article written by Samrhitha A, Stephen Nellis, and Blake Brittain for Reuters, entitled "Apple to Halt Sale of US sales of Series 9, Ultra 2 smartwatches over patent dispute," dated December 18, 2023.

62. Attached hereto as Exhibit 61 is a true and correct copy of an article written by Mark Gurman from Bloomberg, appearing in Time.com, entitled "Apple

Scrambles to Tweak Its Watches in Face of Looming U.S. Ban," dated December 19, 2023.

63. Attached hereto as Exhibit 62 is a true and correct copy of an article written by Joseph Pisani for the Wall Street Journal entitled "Apple Appeals U.S. Ban That Halted Watch Sales," dated December 26, 2023 and printed in the December 27, 2023 Wall Street Journal as "Apple Appeals U.S. Ruling."

64. Attached hereto as Exhibit 63 is a true and correct copy of an article written by Mark Gurman from Bloomberg, printed in the Orange County Register, entitled "How an Email from an Irvine Engineer to Tim Cook Set Apple Watch Saga in Motion," dated December 27, 2023 and reprinted in the January 7, 2024 Orange County Register.

65. Attached hereto as Exhibit 64 is a true and correct copy an article from PYMNTS.com entitled "Apple Wins Legal Victory as Court Lifts Watch Ban," dated December 27, 2023.

66. Attached hereto as Exhibit 65 is a true and correct copy of an article written by Steven Tweedie for Business Insider entitled "Apple Scores Big Break in Apple Watch Sales Ban," dated December 27, 2023.

67. Attached hereto as Exhibit 66 is a true and correct copy of an article written by Aaron Tilley for the Wall Street Journal entitled "Banned Apple Watches

Are Back On Sale ---Appeals court temporarily lifts prohibition imposed over patent dispute," dated December 28, 2023.

68. Attached hereto as Exhibit 67 is a true and correct copy of an article written by Julia Shapero for the Hill entitled "Apple Watches are back on sale after ban paused by federal court," dated December 28, 2023.

69. Attached hereto as Exhibit 68 is a true and correct copy of an article written by Aaron Tilley for the Wall Street Journal entitled "The Entrepreneur Who Bet His Company on a Fight With Apple," dated December 30, 2023, and printed in the January 2, 2024 Wall Street Journal as "CEO Bet His Firm On a Fight With Apple."

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

Executed on January 10, 2023 at Irvine, California.

/s/ Joseph R. Re
Joseph R. Re

LIST OF EXHIBITS

Ex. #	Description	Addendum #
1	Exhibit 21 attached to Masimo's First Amended Complaint, July 7, 2021	MAS-ADD-001-020
2	Order No. 31: Denying Respondent's Motion for Sanctions, April 28, 2022	MAS-ADD-021-035
3	ITC Trial Transcript, Open and Closed Sessions, June 6, 2022, excerpted	MAS-ADD-036-060
4	ITC Trial Transcript, Open and Closed Sessions, June 7, 2022, excerpted	MAS-ADD-061-080
5	ITC Trial Exhibit CX-252	MAS-ADD-081-102
6	ITC Trial Exhibit CX-375C	MAS-ADD-103-107
7	ITC Trial Exhibit CX-378C	MAS-ADD-108-116
8	ITC Trial Exhibit CX-433C	MAS-ADD-117-130
9	ITC Trial Exhibit CX-494C	MAS-ADD-131-141
10	ITC Trial Exhibit CX-1287	MAS-ADD-142-155
11	ITC Trial Exhibit CX-1451 (video)	MAS-ADD-156
12	*Masimo Corp. v. Apple Inc.*, Case No. 8:20-cv-00048-JVS-JDE (C.D. Cal), Trial Exhibit JTX-559	MAS-ADD-157-159
13	ITC Trial Exhibit CPX-52aC	MAS-ADD-160-162
14	ITC Trial Exhibit CPX-58aC	MAS-ADD-163-165
15	ITC Trial Exhibits CPX-19aC, CPX-20aC, and CPX-65aC	MAS-ADD-166-172
16	ITC Trial Exhibit RX-1209C	MAS-ADD-173-178
17	Complainants' Corrected Initial Post-Hearing Brief, July 6, 2022, excerpted	MAS-ADD-179-228
18	Respondent Apple Inc.'s Second Corrected Post-Hearing Brief, Sept. 2, 2022, excerpted	MAS-ADD-229-233
19	Patent Trial and Appeal Board Decision Denying Institution of Apple's Petition No. IPR2022-01273, Jan. 24, 2023	MAS-ADD-234-258
20	Patent Trial and Appeal Board Decision Denying Institution of Apple's Petition No. IPR2022-01274, Jan. 24, 2023	MAS-ADD-259-280
21	Patent Trial and Appeal Board Decision Denying Institution of Apple's Petition No. IPR2022-01275, Jan. 30, 2023	MAS-ADD-281-315

Ex. #	Description	Addendum #
22	Patent Trial and Appeal Board Decision Denying Institution of Apple's Petition No. IPR2022-01276, Jan. 30, 2023	MAS-ADD-316-343
23	Public Interest Statement Of Non-Party Dr. Kevin R. Ward, Feb. 22, 2023	MAS-ADD-344-347
24	Public Interest Statement Of Non-Party Dr. Mitchell Goldstein, Feb. 24, 2023	MAS-ADD-348-354
25	Public Interest Statement Of Non-Party Dr. Peter Pronovost, Feb. 26, 2023	MAS-ADD-355-361
26	Public Interest Statement Of Non-Party Patient Safety Movement Foundation (PSMF), Feb. 27, 2023	MAS-ADD-362-368
27	Public Interest Statement Of Non-Party Medical Device Manufacturers Association (MDMA), Feb. 27, 2023	MAS-ADD-369-375
28	Masimo W1, Hospital Grade Continuous Monitoring of SpO2 and Other Parameters in a Consumer Watch, Whitepaper, Dec. 13, 2022	MAS-ADD-376-392
29	Complainant's Reply to Apple, Inc.'s Response to the Commission's Notice to Review in Part a Final Initial Determination and Request for Written Submissions, June 12, 2023, excerpted	MAS-ADD-393-397
30	Complainants' Request for Judicial Notice of Recent Regulatory Developments for Masimo W1 Watch, Nov. 20, 2023	MAS-ADD-398-420
31	Jeremy Horowitz, *Apple's former top lawyer: $1 billion budget enabled high-risk strategies*, VENTURE BEAT, June 10, 2019	MAS-ADD-421-424
32	*Masimo Corp. v. Apple Inc.*, Case No. 8:20-cv-00048-JVS-JDE (C.D. Cal), Trial Exhibit JTX-358C	MAS-ADD-425-428

Ex. #	Description	Addendum #
33	ITC Inv. No. 337-TA-1266, Respondent Apple Inc.'s Emergency Motion to Suspend Any Remedy or Extend the Target Date and Stay Proceedings Pending Resolution of Any Appeal of the Patent Office's Decision That United States Patent Nos. 10,638,941, 10,595,731, AND 9,572,499 Are Unpatentable, Dec. 7, 2022	MAS-ADD-429-432
34	*Apple v. Masimo Corp.*, Case No. 22-1377-MN (D. Del), Plaintiff Apple Inc.'s Opening Brief in Support of its Motion for Expedited Trial, Feb. 10, 2023	MAS-ADD-433-451
35	Email exchange between counsel for Masimo and counsel for Apple, Dec. 21 and 28, 2023	MAS-ADD-452-453
36	Printout of https://www.apple.com/healthcare/apple-watch/	MAS-ADD-454-461
37	*Masimo Corp. v. Apple Inc.*, Case No. 8:20-cv-00048-JVS-JDE (C.D. Cal), Trial Exhibit JTX-648	MAS-ADD-462-464
38	*Masimo Corp. v. Apple Inc.*, Case No. 8:20-cv-00048-JVS-JDE (C.D. Cal), Trial Exhibit JTX-260	MAS-ADD-465-479
39	*Masimo Corp. v. Apple Inc.*, Case No. 8:20-cv-00048-JVS-JDE (C.D. Cal), Trial Exhibit JTX-393	MAS-ADD-480-482
40	*Masimo Corp. v. Apple Inc.*, Case No. 8:20-cv-00048-JVS-JDE (C.D. Cal), Trial Exhibit JTX-395	MAS-ADD-483-485
41	*Masimo Corp. v. Apple Inc.*, Case No. 8:20-cv-00048-JVS-JDE (C.D. Cal), Trial Exhibit JTX-316	MAS-ADD-486-491
42	*Masimo Corp. v. Apple Inc.*, Case No. 8:20-cv-00048-JVS-JDE (C.D. Cal), Trial Exhibit JTX-317	MAS-ADD-492-494
43	*Masimo Corp. v. Apple Inc.*, Case No. 8:20-cv-00048-JVS-JDE (C.D. Cal), Trial Exhibit JTX-1719	MAS-ADD-495-498

Ex. #	Description	Addendum #
44	*Masimo Corp. v. Apple Inc.*, Case No. 8:20-cv-00048-JVS-JDE (C.D. Cal), Trial Exhibit JTX-263	MAS-ADD-499-509
45	*Masimo Corp. v. Apple Inc.*, Case No. 8:20-cv-00048-JVS-JDE (C.D. Cal), Trial Exhibit JTX-2070	MAS-ADD-510-512
46	*The Trouble With Patent-Troll-Hunting*, ECONOMIST, Dec. 14, 2019	MAS-ADD-513-515
47	JENNY CHAN, MARK SELDEN & PUN NGAI, DYING FOR AN IPHONE – APPLE, FOXCONN, AND THE LIVES OF CHINA'S WORKERS (2020), excerpted	MAS-ADD-516-544
48	*Masimo Corp. v. Apple Inc.*, Case No. 8:20-cv-00048-JVS-JDE (C.D. Cal), Trial Exhibit JTX-736	MAS-ADD-545-547
49	Apple 2020 Event (video)	MAS-ADD-548
50	Anthony Pearson, *Should You Trust the New Apple Watch on Blood Oxygen Readings? – The Skeptical Cardiologist peels back the hype*, MEDPAGETODAY, Sept. 21, 2020	MAS-ADD-549-556
51	Geoffrey A. Fowler, *The new Apple Watch says my lungs may be sick. Or perfect. It can't decide*, WASHINGTON POST, Sept. 23, 2020	MAS-ADD-557-561
52	Joanna Stern, *Apple Watch Series 6 and SE Review: Watch Out for the Upsell*, WALL STREET JOURNAL, Sept. 24, 2020	MAS-ADD-562-569
53	Dieter Bohn, *Apple Watch Series 6 review: minute improvements*, VERGE, Oct. 1, 2020	MAS-ADD-570-580
54	Apple 2022 Event (video)	MAS-ADD-581
55	Blake Brittain, *Apple lawsuits say health monitoring company Masimo copied Apple Watch*, REUTERS, Oct. 20, 2022	MAS-ADD-582-589
56	*Apple v. Masimo Corp.*, Case No. 22-1377-MN (D. Del), Complaint, Oct. 20, 2022, excerpted	MAS-ADD-590-593

Ex. #	Description	Addendum #
57	*Apple v. Masimo Corp.*, Case No. 22-1378-UNA (D. Del), Complaint, Oct. 20, 2022, excerpted	MAS-ADD-594-597
58	*Masimo Corp. v. Apple Inc.*, Case No. 8:20-cv-00048-JVS-JDE (C.D. Cal), Waydo Trial Testimony, Apr. 19, 2023, excerpted	MAS-ADD-598-606
59	*Masimo Corp. v. Apple Inc.*, Case No. 8:20-cv-00048-JVS-JDE (C.D. Cal), Hotelling Trial Testimony, Apr. 20, 2023, excerpted	MAS-ADD-607-622
60	Samrhitha A, Stephen Nellis & Blake Brittain, *Apple to Halt Sale of US sales of Series 9, Ultra 2 smartwatches over patent dispute*, REUTERS, Dec. 18, 2023	MAS-ADD-623-640
61	Mark Gurman, *Apple Scrambles to Tweak Its Watches in Face of Looming U.S. Ban*, TIME, Dec. 19, 2023	MAS-ADD-641-645
62	Joseph Pisani, *Apple Appeals U.S. Ban That Halted Watch Sales*, WALL STREET JOURNAL, Dec. 26, 2023	MAS-ADD-646-649
63	Mark Gurman, *How an Email from an Irvine Engineer to Tim Cook Set Apple Watch Saga in Motion*, ORANGE COUNTY REGISTER, Dec. 27, 2023	MAS-ADD-650-662
64	*Apple Wins Legal Victory as Court Lifts Watch Ban*, PYMNTS, Dec. 27, 2023	MAS-ADD-663-665
65	Steven Tweedie, *Apple Scores Big Break in Apple Watch Sales Ban*, BUSINESS INSIDER, Dec. 27, 2023	MAS-ADD-666-668
66	Aaron Tilley *Banned Apple Watches Are Back On Sale – Appeals court temporarily lifts prohibition imposed over patent dispute*, WALL STREET JOURNAL, Dec. 28, 2023	MAS-ADD-669-672
67	Julia Shapero, *Apple Watches are back on sale after ban paused by federal court*, THE HILL, Dec. 28, 2023	MAS-ADD-673-679
68	Aaron Tilley, *The Entrepreneur Who Bet His Company on a Fight With Apple*, WALL STREET JOURNAL, Dec. 30, 2023	MAS-ADD-680-686

Rule 25.1(e)(1)(B) Statement: The material omitted from the following Addendum pages contains Masimo confidential competitively sensitive information regarding Masimo's product development for the Masimo Watch project that Masimo designated as Confidential Business Information under the Commission's Administrative Protective Order: MAS-ADD-002-020, MAS-ADD-023-034, MAS-ADD-104-107, MAS-ADD-109-116, MAS-ADD-118-130, MAS-ADD-132-141, MAS-ADD-181-225, and MAS-ADD-395-396. The material omitted from the following Addendum pages contains testimony that discusses confidential competitively sensitive information regarding Masimo's product development for the Masimo Watch project that Masimo designated as Confidential Business Information under the Commission's Administrative Protective Order: MAS-ADD-041, MAS-ADD-047-059, MAS-ADD-063-067, MAS-ADD-070, MAS-ADD-074-079, and MAS-ADD-174-178. The material omitted from the following Addendum pages shows Masimo prototypes as part of Masimo's confidential product development for the Masimo Watch project that Masimo designated as Confidential Business Information under the Commission's Administrative Protective Order: MAS-ADD-161-162, MAS-ADD-164-165, and MAS-ADD-167-172. The material omitted from Addendum page MAS-ADD-226 contains information that Appellant Apple Inc. designated as Confidential Business Information under the Commission's Administrative Protective Order regarding its development of the Apple Watch.

UNITED STATES INTERNATIONAL TRADE COMMISSION

Washington, D.C.

In the Matter of	
CERTAIN LIGHT-BASED PHYSIOLOGICAL MEASUREMENT DEVICES AND COMPONENTS THEREOF	**Inv. No. 337-TA-1276**

ORDER NO. 1: PROTECTIVE ORDER

(August 18, 2021)

WHEREAS, documents and information may be sought, produced or exhibited by and among the parties to the above captioned proceeding, which materials relate to trade secrets or other confidential research, development or commercial information, as such terms are used in the Commission's Rules, 19 C.F.R. § 210.5;

IT IS HEREBY ORDERED THAT:

1. Confidential business information is information which concerns or relates to the trade secrets, processes, operations, style of work, or apparatus, or to the production, sales, shipments, purchases, transfers, identification of customers, inventories, amount or source of any income, profits, losses, or expenditures of any person, firm, partnership, corporation, or other organization, or other information of commercial value, the disclosure of which is likely to have the effect of either (i) impairing the Commission's ability to obtain such information as is necessary to perform its statutory functions; or (ii) causing substantial harm to the competitive position of the person, firm, partnership, corporation, or other organization from which the information was obtained, unless the Commission is required by law to disclose such

information. The term "confidential business information" includes "proprietary information" within the meaning of section 777(b) of the Tariff Act of 1930 (19 U.S.C. § 1677f(b)).

2(a). Any information submitted, in pre hearing discovery or in a pleading, motion, or response to a motion either voluntarily or pursuant to order, in this investigation, which is asserted by a supplier to contain or constitute confidential business information shall be so designated by such supplier in writing, or orally at a deposition, conference or hearing, and shall be segregated from other information being submitted. Documents shall be clearly and prominently marked on their face with the legend: "CONFIDENTIAL BUSINESS INFORMATION, SUBJECT TO PROTECTIVE ORDER," or a comparable notice. Such information, whether submitted in writing or in oral testimony, shall be treated in accordance with the terms of this protective order.

(b). The Administrative Law Judge or the Commission may determine that information alleged to be confidential is not confidential, or that its disclosure is necessary for the proper disposition of the proceeding, before, during or after the close of a hearing herein. If such a determination is made by the Administrative Law Judge or the Commission, opportunity shall be provided to the supplier of such information to argue its confidentiality prior to the time of such ruling.

3. In the absence of written permission from the supplier or an order by the Commission or the Administrative Law Judge, any confidential documents or business information submitted in accordance with the provisions of paragraph 2 above shall not be disclosed to any person other than: (i) outside counsel for parties to this investigation, including necessary secretarial and support personnel assisting such counsel; (ii) qualified persons taking testimony involving such documents or information and necessary stenographic and clerical personnel thereof; (iii)

technical experts and their staff who are employed for the purposes of this litigation (unless they are otherwise employed by, consultants to, or otherwise affiliated with a non-governmental party, or are employees of any domestic or foreign manufacturer, wholesaler, retailer, or distributor of the products, devices or component parts which are the subject of this investigation); (iv) the Commission, the Administrative Law Judge, the Commission staff, and personnel of any governmental agency as authorized by the Commission; (v) the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this investigation or related proceedings, or (b) in internal investigations, audits, reviews, evaluations relating to the programs, personnel, and operations of the Commission including under to 5 U.S.C. Appendix 3; and (vi) U.S. government employees and contract personnel, solely for cybersecurity purposes.[1]

4. Confidential business information submitted in accordance with the provisions of paragraph 2 above shall not be made available to any person designated in paragraph 3(i)[2] and (iii) unless he or she shall have first read this order and shall have agreed, by letter filed with the Secretary of this Commission: (i) to be bound by the terms thereof; (ii) not to reveal such confidential business information to anyone other than another person designated in paragraph 3; and (iii) to utilize such confidential business information solely for purposes of this investigation. The letter shall also include the following acknowledgement:

> I, the undersigned, on behalf of _____, acknowledge that information submitted for purposes of this Investigation may be disclosed to and used:
>
> (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in

[1] *See* Commission Administrative Order 16-01 (Nov. 7, 2015).
[2] Necessary secretarial and support personnel assisting counsel need not sign onto the protective order themselves because they are covered by counsel's signing onto the protective order.

> internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or
> (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. I understand that all contract personnel will sign appropriate nondisclosure agreements.

5. If the Commission or the Administrative Law Judge orders, or if the supplier and all parties to the investigation agree, that access to, or dissemination of information submitted as confidential business information shall be made to persons not included in paragraph 3 above, such matter shall only be accessible to, or disseminated to, such persons based upon the conditions pertaining to, and obligations arising from this order, and such persons shall be considered subject to it, unless the Commission or the Administrative Law Judge finds that the information is not confidential business information as defined in paragraph 1 thereof.

6. (a). Any confidential business information submitted to the Commission or the Administrative Law Judge in connection with a motion or other proceeding within the purview of this investigation shall be submitted under seal pursuant to paragraph 2 above. Any portion of a transcript in connection with this investigation containing any confidential business information submitted pursuant to paragraph 2 above shall be bound separately and filed under seal. When any confidential business information submitted in accordance with paragraph 2 above is included in an authorized transcript of a deposition or exhibits thereto, arrangements shall be made with the court reporter taking the deposition to bind such confidential portions and separately label them "CONFIDENTIAL BUSINESS INFORMATION, SUBJECT TO PROTECTIVE ORDER." Before a court reporter or translator receives any such information, he or she shall have first read this order and shall have agreed in writing to be bound by the terms thereof. Alternatively, he or she shall sign the agreement included as Attachment A hereto.

Copies of each such signed agreement shall be provided to the supplier of such confidential business information and the Secretary of the Commission.

(b). Submitters[3] are strongly encouraged to encrypt nonpublic documents that are electronically transmitted to the Commission to protect your sensitive information from unauthorized disclosure. The USITC secure drop-box system and the Electronic Document Information System (EDIS) use Federal Information Processing Standards (FIPS) 140-2 cryptographic algorithms to encrypt data in transit. Submitting your nonpublic documents by a means that does not use these encryption algorithms (such as by email) may subject your firm's nonpublic information to unauthorized disclosure during transmission. If you choose a non-encrypted method of electronic transmission, the Commission warns you that the risk of such possible unauthorized disclosure is assumed by you and not by the Commission.

7. The restrictions upon, and obligations accruing to, persons who become subject to this order shall not apply to any information submitted in accordance with paragraph 2 above to which the person asserting the confidential status thereof agrees in writing, or the Commission or the Administrative Law Judge rules, after an opportunity for hearing, was publicly known at the time it was supplied to the receiving party or has since become publicly known through no fault of the receiving party.

8. The Commission, the Administrative Law Judge, and the Commission investigative attorney acknowledge that any document or information submitted as confidential business information pursuant to paragraph 2 above is to be treated as such within the meaning of 5 U.S.C. § 552(b)(4) and 18 U.S.C. § 1905, subject to a contrary ruling, after hearing, by the

[3] "Submitters" of confidential business information are the same as "suppliers" of confidential business information as that term is used in the context of this order. *See* Commission Administrative Order 16-01 (Nov. 7, 2015).

Commission or its Freedom of Information Act Officer, or the Administrative Law Judge. When such information is made part of a pleading or is offered into the evidentiary record, the data set forth in 19 C.F.R. § 201.6 must be provided except during the time that the proceeding is pending before the Administrative Law Judge. During that time, the party offering the confidential business information must, upon request, provide a statement as to the claimed basis for its confidentiality.

9. Unless a designation of confidentiality has been withdrawn, or a determination has been made by the Commission or the Administrative Law Judge that information designated as confidential, is no longer confidential, the Commission, the Administrative Law Judge, and the Commission investigative attorney shall take all necessary and proper steps to preserve the confidentiality of, and to protect each supplier's rights with respect to, any confidential business information designated by the supplier in accordance with paragraph 2 above, including, without limitation: (a) notifying the supplier promptly of (i) any inquiry or request by anyone for the substance of or access to such confidential business information, other than those authorized pursuant to this order, under the Freedom of Information Act, as amended (5 U.S.C. § 552) and (ii) any proposal to redesignate or make public any such confidential business information; and (b) providing the supplier at least seven days after receipt of such inquiry or request within which to take action before the Commission, its Freedom of Information Act Officer, or the Administrative Law Judge, or otherwise to preserve the confidentiality of and to protect its rights in, and to, such confidential business information.

10. If while an investigation is before the Administrative Law Judge, a party to this order who is to be a recipient of any business information designated as confidential and submitted in accordance with paragraph 2 disagrees with respect to such a designation, in full or in part, it

shall notify the supplier in writing, and they will thereupon confer as to the status of the subject information proffered within the context of this order. If prior to, or at the time of such a conference, the supplier withdraws its designation of such information as being subject to this order, but nonetheless submits such information for purposes of the investigation; such supplier shall express the withdrawal, in writing, and serve such withdrawal upon all parties and the Administrative Law Judge. If the recipient and supplier are unable to concur upon the status of the subject information submitted as confidential business information within ten days from the date of notification of such disagreement, any party to this order may raise the issue of the designation of such a status to the Administrative Law Judge who will rule upon the matter. The Administrative Law Judge may sua sponte question the designation of the confidential status of any information and, after opportunity for hearing, may remove the confidentiality designation.

11. No less than 10 days (or any other period of time designated by the Administrative Law Judge) prior to the initial disclosure to a proposed expert of any confidential information submitted in accordance with paragraph 2, the party proposing to use such expert shall submit in writing the name of such proposed expert and his or her educational and detailed employment history to the supplier. If the supplier objects to the disclosure of such confidential business information to such proposed expert as inconsistent with the language or intent of this order or on other grounds, it shall notify the recipient in writing of its objection and the grounds therefore prior to the initial disclosure. If the dispute is not resolved on an informal basis within ten days of receipt of such notice of objections, the supplier shall submit immediately each objection to the Administrative Law Judge for a ruling. If the investigation is before the Commission the matter shall be submitted to the Commission for resolution. The submission of such confidential business information to such proposed expert shall be withheld pending the ruling of the

Commission or the Administrative Law Judge. The terms of this paragraph shall be inapplicable to experts within the Commission or to experts from other governmental agencies who are consulted with or used by the Commission.

12. If confidential business information submitted in accordance with paragraph 2 is disclosed to any person other than in the manner authorized by this protective order, the party responsible for the disclosure must immediately bring all pertinent facts relating to such disclosure to the attention of the supplier and the Administrative Law Judge and, without prejudice to other rights and remedies of the supplier, make every effort to prevent further disclosure by it or by the person who was the recipient of such information.

13. Nothing in this order shall abridge the right of any person to seek judicial review or to pursue other appropriate judicial action with respect to any ruling made by the Commission, its Freedom of Information Act Officer, or the Administrative Law Judge concerning the issue of the status of confidential business information.

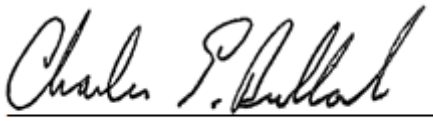
14. Upon final termination of this investigation, each recipient of confidential business information that is subject to this order shall assemble and return to the supplier all items containing such information submitted in accordance with paragraph 2 above, including all copies of such matter which may have been made. Alternatively, the parties subject to this order may, with the written consent of the supplier, destroy all items containing confidential business information and certify to the supplier (or his counsel) that such destruction has taken place. This paragraph shall not apply to the Commission, including its investigative attorney, and the Administrative Law Judge, which shall retain such material pursuant to statutory requirements and for other recordkeeping purposes, but may destroy such material (including electronic media containing such information) in its possession which it regards as surplusage.

Notwithstanding the above paragraph, confidential business information may be transmitted to a district court pursuant to Commission Rule 210.5(c).

15. If any confidential business information which is supplied in accordance with paragraph 2 above is supplied by a nonparty to this investigation, such a nonparty shall be considered a "supplier" as that term is used in the context of this order.

16. Each nonparty supplier shall be provided a copy of this order by the party seeking information from said supplier.

17. The Secretary shall serve a copy of this order upon all parties.



Charles E. Bullock
Chief Administrative Law Judge

Attachment A

NONDISCLOSURE AGREEMENT FOR REPORTER/STENOGRAPHER/TRANSLATOR

I, _____, do solemnly swear or affirm that I will not divulge any information communicated to me in any confidential portion of the investigation or hearing in the matter of *Certain*_____, Investigation No. 337-TA-___, except as permitted in the protective order issued in this case. I will not directly or indirectly use, or allow the use of such information for any purpose other than that directly associated with my official duties in this case.

Further, I will not by direct action, discussion, recommendation, or suggestion to any person reveal the nature or content of any information communicated during any confidential portion of the investigation or hearing in this case.

I also affirm that I do not hold any position or official relationship with any of the participants in said investigation.

I am aware that the unauthorized use or conveyance of information as specified above is a violation of the Federal Criminal Code and punishable by a fine of up to $10,000, imprisonment of up to ten (10) years, or both.

Signed _____

Dated _____

Firm or affiliation _____

CERTAIN LIGHT-BASED PHYSIOLOGICAL MEASUREMENT DEVICES AND COMPONENTS THEREOF **Inv. No. 337-TA-1276**

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **ORDER** has been served upon the following parties as indicated, on **August 18, 2021**.

Lisa R. Barton, Secretary
U.S. International Trade Commission
500 E Street, SW, Room 112
Washington, DC 20436

On Behalf of Complainants Masimo Corporation and Cercacor Laboratories, Inc.:

Jonathan Bachand, Esq.
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☐ Via Hand Delivery
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☐ Via Hand Delivery
☐ Via Express Delivery
☐ Via First Class Mail
☒ Other: Service to Be Completed by Complainants